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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,068	03/05/2002	John Carbone	SPINE 3.0-381	6711
530	7590	07/01/2004	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/091,068	Applicant(s) CARBONE ET AL.	
	Examiner Jessica R Baxter	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2002; 05 Sept 2003; 01 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
 4a) Of the above claim(s) 11, 19 and 44-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-18 and 20-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09052003_05172002</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

1. The drawings are objected to because there are two figures labeled FIG. 18. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Election/Restrictions

2. Applicant's election of Group I Species A in the reply filed on April 1, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

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3. Claims 11, 19 and 44-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 1, 2004.

Claim Objections

4. Claims 1 is objected to because the term “transverse” is used. Transverse is defined as made at right angles to the long axis of a body. From the specification and figures it appears that transverse is not limited to right angles since none of the figures are shown with bores formed at right angles, however this is not clear in claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 3, 5, 6-10, 12, 15-17, 20, 28-32, 34, 35, 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,891,145 to Morrison et al.

Morrison discloses a bone fixation assembly comprising: a coupling element (30) having a first bore (34) coaxial (axis 38) with a first longitudinal axis and a second bore coaxial (axis 45) with a second longitudinal axis, wherein said first and second longitudinal axes are transverse to one another; and an anchoring element (20) assembled with said coupling element, said anchoring element having a first end for insertion into bone (Column

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5 lines 24-39), wherein said coupling element has an upper end and a lower end, said first bore extending from said upper end toward said lower end and said second bore extending from said lower end toward said upper end (FIG. 11), wherein said first and second bores are in communication with one another between said upper and lower ends of said coupling element (FIG. 11), wherein said anchoring element projects from said lower end of said coupling element (FIG. 11), wherein said anchoring element is a separate member assembled with said coupling element so that said coupling element and said anchoring element are movable relative to one another, wherein said second bore includes a seat adjacent (50) said lower end of said coupling element, and wherein said seat is adapted to engage said anchoring element (fig. 11), wherein said anchoring element has a head having a substantially spherical underside adapted to engage said seat (Column 5 lines 40-46), wherein said seat is shaped for facilitating pivotal movement of said coupling element and said anchoring element relative to one another, wherein said seat is substantially conical (FIGS. 7,9) with sidewalls tapering inwardly toward said lower end of said coupling element, a locking element (70) engageable with said coupling element, wherein said locking element urges a stabilizing rod (80) toward said lower end of said coupling element which in turn forces said head of said anchoring element against said seat for locking said coupling element and said anchoring element from further movement relative to one another (FIG. 2).

7. Claims 1-7, 12, 19, 20-24, 28-31 and 37-41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,403,314 to Currier.

Currier discloses a coupling element having a first bore coaxial with a first longitudinal axis and a second bore coaxial with a second longitudinal axis, wherein said first and second longitudinal axes are transverse to one another (FIG. 3, 5, 6, 8); and an

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anchoring element assembled with said coupling element (FIG. 1), said anchoring element having a first end for insertion into bone, wherein said coupling element has an upper end and a lower end, said first bore extending from said upper end toward said lower end and said second bore extending from said lower end toward said upper end wherein said upper end of said coupling element defines a first plane and said lower end of said coupling element defines a second plane, and wherein said first and second planes intersect one another (FIGS. 3-8).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 13, 14 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. 145 in view of U.S. Patent No. 6,280,442 to Barker et al.

Morrison discloses the claimed invention except for the concave neck portion having a smaller diameter than the threaded portion. Barker teaches an anchoring portion with a concave neck that is utilized with a coupling element in order to allow for multi-axial movement of the anchoring portion with respect to the coupling element (Column 7 lines 9-21). It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to provide the device of Morrison with the concave neck in order to allow for multi-axial movement of the anchoring portion relative to the coupling element.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. '145 in view of U.S. Patent No. 5,554,157 to Errico et al.

Morrison discloses the claimed invention except for the anchoring portion has a neck portion which has a smaller diameter than the threaded portion. Errico teaches that a smaller neck portion is provided in order to allow the screw to be locked at a variety of angles while still being securely joined to the coupling element (Column 5 lines 40-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Morrison with the smaller neck of Errico in order to allow the screw to be locked at a variety of angles while still being securely joined to the coupling element.

11. Claims 18 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. 145 in view of U.S. Patent No. 5,725,527 to Biedermann et al.

Morrison discloses the claimed invention except for the chamfered surface extending from one of said opening surfaces to said inner surface of the U-shaped openings.

Biedermann teaches that a chamfered surface is provided so that the rod may be easily inserted into and removed from the opening and a better form fit may be formed with the rod (Column 2 lines 9-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the U-Shaped openings of Morrison with a chamfered surface in order to allow the rod to be easily inserted and removed and to provide a better form fit with the rod.

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12. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. '145 in view of U.S. Patent No. 5,474,551 to Finn et al

Morrison discloses the claimed invention except for the notches on the outer surface of the coupling element. Finn teaches that notches are provided on the outside surface of a coupling element in order to accommodate a wrench that is used to stabilize the coupler body while the anchoring portion is being tightened into place (Column 4 lines 60-65). IT would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the coupling element of Morrison with the notches of Finn in order to stabilize the coupling element while the anchoring element is being tightened into place.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,084,048 to Jacob et al.

U.S. Patent No. 5,133,717 to Chopin

U.S. Patent No. 6,554,834 to Crozet et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3731


jrb


DAVID O. REIP
PRIMARY EXAMINER